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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/541,795	03/31/2000	James Link	6446.US.P2	3564

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STEVEN F. WEINSTOCK
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

[REDACTED] EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
1624	[REDACTED]

DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/541,795	Applicant(s) James Link et al
Examiner SUDHAKER PATEL,D.Sc.Tech.	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Mar 21, 2003
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above, claim(s) 20-25 and 48-60 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 and 26-46 is/are rejected.
- 7) Claim(s) 47 is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

Art Unit: 1624

DETAILED ACTION

I.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/21/03 has been entered.

II.

Election/Restriction

Applicants' arguments, remarks and suggestions are considered favorably, and found persuasive. Accordingly, the restriction/election has been modified as follows:

Group I : Claims 1-19,26-47 drawn to compounds and composition of Formula (I) and Formula (III) which are derivatives of core: "Ar-S-phenyl-CH =CH=CO-N =" i.e. having a bridge of cinnamide.

Group II : Claim 24 drawn to intermediates and compounds represented by Formula (II) which is not an amide.

Group III : Claims 52-60 drawn to method of use for the compounds of Formulae (I) and (III) which bind to the interaction-domain of LFA-1.

Art Unit: 1624

Group IV : Claim 25 drawn to method of preparing compounds of Formula (II).

Group V :Claims 20-21, 48 drawn to method of inhibiting inflammation using compounds and composition of Formula (I) and Formula (III).

Group VI : Claims 22,23 drawn to method of suppressing immune response using compounds and composition of Formula (I) and Formula (III).

Group VII :Claims 49-51 drawn to method of treating an inflammatory condition using compounds and composition of Formula (I) and Formula (III).

Applicants' election without traverse of invention of Group I and Example 399 as species in paper # 17 dated 3/21/03 is acknowledged.

Invention of Group I consists of claims 1-19,26-~~57~~¹⁴, and the elected species in Example 399, line 13, to page 350, line 7, and claim 12, page 461, lines 1-2 which is:

“ 3-(3-Carboxypiperidine-1-yl)phenyl-(2,3-dichloro)-4-(E-((4-morpholino)carbonyl)ethenyl)phenylsulfide”.

Claims 20-25,48-60 are withdrawn from further consideration by the examiner as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 809.02 and 821.01 - 821.03.

The restriction/election is considered proper, is maintained.

Accordingly, action on merits follows.

Art Unit: 1624

III.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-19,26-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6110922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the definitions of variables Ar,R1-R5,R10,R11 in the instant claims overlap with the reference.

Art Unit: 1624

3. Claims 1-19,26-57 are directed to the same invention as that of claims 1-15 of commonly assigned U.S.P. 6110922. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

4. Claims 1-19,26-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19,26-31,34-45,47-57 of copending U.S. Application Sr. No.09695040 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the definitions of variables Ar,R1-R5,R10,R11 in the instant claims overlap with the reference .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

IV.

Failure to comply with 37 CFR 1.141(a)

Art Unit: 1624

Claims 12,13 are rejected as failing to comply with 37 CFR 1.141(a). Claims 12,13 are more than a reasonable number of species.

In re Fressola, 22 USPQ 2nd 1828, indicates that the Examiner may reject for applicants' failure to follow a Rule. 37 CFR 1.141(a) provides for a reasonable number of species to be examined with the genus. Claims 12,13 are an aggravated, multiple page, example of listing ultimate species in one claim. Claim 12 and claim 13 are not a Markush claim, see claim 1, and are lists of ultimate species. See the directive of Richard A. Wahl, August 10, 1968 (copy is enclosed).

V.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19,26-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

(A). Claim 1 of amendment paper # 7 dated 1/29/02 on page 142 recites substitutents on to Ar variables : " l. Aminocarbonyl, t. Carboxamide". It is not very clear as to what applicants want to claim as a substituent on a ring because a group: -CONH2 = NH2CO-. Correction is required.

Art Unit: 1624

(B). Claim 1 recites the term: “ substituted by one or more than one “ for variables R10, R11, Ar, R3. It is not exactly clear as to what is meant by: “ more than one”. It can be 2 or infinite. Correction is required.

(C). Independent Claim 47 recites : “ A pharmaceutical composition...diarylsulfide...”, and claim 19 which is dependent on claim 1 also recites: “ A pharmaceutical compositioncompound of claim 1”. Correction is required to avoid duplication.

(D). Claims 45 and 46 recite : “ about 50 percent, and about 100 percent respectively”. It is not very clear as to what applicants want to claim by: “ about”. Correction is required.

(F). Claim 44 recite : “ inhibitory activity in an ICAM-1/LFA-1 biochemical interaction assay or an ICAM-3/JY-8 cell adhesion assay”. “Inhibitory activity” as claimed herein does not recite any dosage or concentration of the compound of a generic claim 47 which even does not exactly represent the chemical structure.

MPEP 806.05(h) provides for restriction of method of use claims, where they show more than one use of the compounds.

The utility statement in claim 54 cannot be acceptable as one specific utility. The recent utility guidelines set up by USPTO require applicants to meet the requirements as stated in *Brenner v. Manson* in 148 USPQ 689, which requires that utility be developed to a point where “specific benefits exists in currently available form” similar is the “immediate benefit to the public: standard set forth in the concurring opinion of *In re Hartop*, 135 USPQ 419 is whether the

Art Unit: 1624

invention has been brought to such perfection as to be capable of practical employment. This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

The "how to use" requirements of 35 U.S.C. 112 are not met by disclosing only a pharmacological activity of the claimed compounds if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Driedrich (CCPA 1963) 318 F.2d 946, 138 USPQ 128; In re Garner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138. Thus, where the compounds as claimed in claim 47 are not structurally similar to known compounds having the same activity and their pharmaceutical properties could not be predicted based on their structure/chemical molecule, a disclosure that they possess a particular activity against a biological inhibitory in an ICAM-1/LF-1 or an ICAM-3/JY-8 assays. May not suffice as a description of how to use as required by 35 U.S.C. 112. In re Moureu et al (CCPA 1965) 345 F2d 595, 145 USPQ 452. activity.

VI.

Claim Objections

Independent Claim 47 is objected to because of the following informalities: Independent claim 37 does not define any structure or formula for the claimed diaryl sulfide cinnamide. This claim is a duplicate of main claim 1. Appropriate correction is required.

Preliminary search revealed prior art reference Alain Platel et al (U.S.P. 4808582). Note, Platel teaches making of Cinnamoic compounds which are useful as drugs having stimulating, protecting, and correcting activities of the cerebral functions. The reference is cited to show that

Art Unit: 1624

Phenyl substituted by Cinnamoic moiety has biological utility. Platel can not be used here as it does not suggest or teach to arrive at the instant compounds.

VII.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc.Tech. whose telephone number is (703) 308 4709.

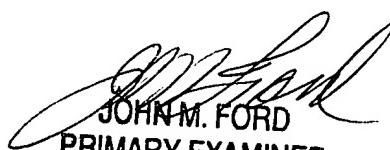
The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at 703 308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

S.p.

April 9, 2003.


JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624
1624